

Testing Method Recommendations for Filth in Gummy Products on IA 99-46

Date: 2-7-2024

**Please note, this recommendation is intended to provide supplemental general information to private laboratories on methods of analysis and test portion sizes of gummy products. This document does not outline all the analytical method or worksheet requirements for packages being submitted for FDA review. **

Please refer to the current FDA Laboratory Manual, Volume III, Section 7 for comprehensive information on private laboratory package requirements and the review process:

<https://www.fda.gov/media/73540/download>

Product Information:

The FDA has found various gummy products that appear to be adulterated because they contain filth (including but not limited to fibers, insect fragments, animal hairs, metal fragments, plastic pieces, paint chips, and/or feather barbules). In general, when testing gummy products for filth, all filth should be identified and quantified.

Analytical Protocol:

Samples should consist of at least six 1 pound subsamples for official analysis.

Sample Methods:

- Examine a 100-gram test portion of the gummy product using AOAC 971.34(a) – Filth in Candy. After digesting sample, sieve over #230 sieve if necessary.
- If a large amount of residue remains using AOAC 971.34(a), examine a 225-gram test portion of gummy product using AOAC 971.34(c).
- **Count all filth elements** and report findings according to AOAC 970.66. Note that other extraneous materials (e.g., fibers, paint chips, etc.) need to be described and reported by type and appropriate quantitative figure.

Quality Assurance:

Laboratory must follow the methodology specified in the private laboratory package submission. Any method modifications or deviations to the cited method must be explained and validation must be documented.

FDA does not endorse any private laboratory firms, nor requires specific methods to be used for Private Laboratory Analytical Packages (PLAPs). Information herein is provided as a courtesy, but private laboratories are not required to use them. The requirements state the method should be locally validated and should adequately identify and or quantitate the violative analyte(s). The information herein may also provide supplementary sampling, method information and/or sample preparation information to assist private laboratories who are analyzing products being held under Detention Without Physical Examination (DWPE) as part of an Import Alert to assist private laboratories with submitting scientifically sound PLAPS as testimony pursuant to FD&C Act section 801 and 21 CFR 1.94 or FD&C Act section 422(b) and 21 CFR 1.1107.